MAY - 8 2012

Section 5- 510(k) Summary

Submitter :	St Jude Medical, CRMD 15900 Valley View Court Sylmar, CA 91324 Establishment Registration Number: 2017865
Contact Person :	Colleen Canan Staff Regulatory Affairs Specialist Phone (818) 493 2960 Fax (818) 493 3615
Date Prepared :	January 27, 2012
Trade Name :	CPS Excel™ MediGuide Enabled™ Guidewire and accessories
Classification :	Class II – 21 CFR 870.1330 Catheter, Guidewire
Product Code :	DQX
Predicate Device:	The subject device is equivalent to the following St Jude Medical and MediGuide Devices St Jude Medical CPS Courier™ Guidewire (K073082) cleared on January 9, 2008 MediGuide Guided Measurement Catheter (GMC) (K091781) cleared on October 16, 2009
Device Description :	The St. Jude Medical CPS Excel™, MediGuide Enabled™ guidewire is a MediGuide enabled guidewire with a hydrophilic coating. The CPS Excel, MediGuide Enabled guidewire contains a magnetic sensor allowing it to be visualized using the MediGuide system
Intended Use:	The St. Jude Medical™ CPS Excel™ MediGuide Enabled™ guidewire is intended for use with the MediGuide system to enable real-time tip positioning and navigation within the coronary and peripheral vasculature. The MediGuide system is intended for use as an adjunct to fluoroscopy
Comparison to Predicate Devices	The St Jude Medical CPS Excel MediGuide Enabled guidewire has a similar intended use and the same fundamental scientific technology as the

predicate devices. All technological characteristics of CPS Excel MediGuide Enabled guidewire kit are substantially equivalent to the predicate devices including packaging, biocompatibility, sterilization, and labeling. Where differences exist between the subject device and the predicate devices performance testing demonstrated that these differences do not adversely affect the safety and effectiveness of the subject device.

Conclusion : St Jude Medical considers the CPS Excel MediGuide Enabled guidewire kit to be equivalent to the predicate devices listed above. This conclusion is based upon the device similarities in design, technological characteristics, principles of operation, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 13 2012

St. Jude Medical
c/o Ms. Colleen Canan
Staff Regulatory Submission Specialist
15900 Valley View Court
Sylmar, CA 91342

Re: K120298
CPS Excel™ MediGuide Enabled™ Guidewire and accessories
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: II (two)
Product Code: 74 DQX
Dated (Date on orig SE ltr): April 6, 2012
Received (Date on orig SE ltr): April 10, 2012

Dear Ms. Canan:

This letter corrects our substantially equivalent letter of May 8, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

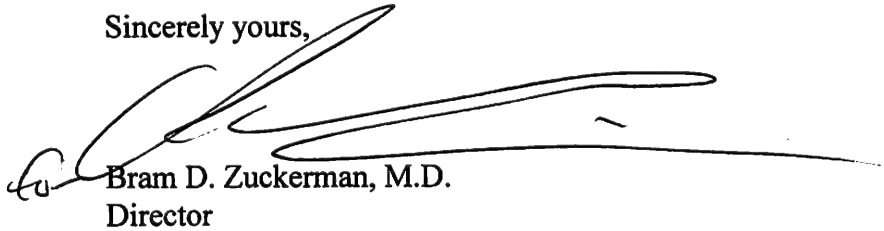
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

Device Name: CPS Excel™ MediGuide Enabled™ Guidewire
Models DS2M027, DS2M028, DS2M029

Indications for Use:

The St. Jude Medical CPS Excel™ MediGuide Enabled™Guidewire is intended for use with the MediGuide™ System to enable real-time tip positioning and navigation within the coronary and peripheral vasculature (such as to facilitate left heart lead implantation). The MediGuide system is intended for use as an adjunct to fluoroscopy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120298